K002631

OCT 2 3 2000

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510(k) Summary

Date Prepared: May 10, 2000
Name of contact person: Frank Neumann
Device Trade Name: eemagine EEG software
Classification Name: Electroencephalograph
Common/Usual Name: Electroencephalograph Software
Predicate substantially equivalent devices:
K980477, SAM Technology, Inc., IMAGEVUE EEG Software
K974718, Persyst Development Corporation, Persyst Prism
K950117, Persyst Consulting Services Inc., Persyst Spike Detector

Indications for Use (Intended Use): The software is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects for the visualization of human brain function by fusing a variety of EEG information with rendered images of an idealized head model and an idealized MRI image.

Description of Device: The eemagine EEG software is a software only product. It runs on a personal computer and requires no specialized hardware. It displays digitized EEG signals, power spectra, topographic maps, etc. It displays electrical brain activity correlated to anatomical brain information, which is provided by means of an idealized MRI and head model. These functions are all controlled and interpreted by the user. The eemagine EEG software imports digital EEG data (in a variety of formats) and permits it visualization. The digitized EEG input is read from a file on the personal computer (or available across the network). The software also provides a report generator to transfer relevant information, such as patient and recording information, event information, topographic images and images of brain activity, to a printable document.
Neither the computer nor the software control the delivery of energy, the administration of drugs, or another form of life sustaining function of the subject.

Safety and Effectiveness, Comparison to Predicate Devices: Both eemagine EEG and Persyst Prism support the following digital EEG plots: EEG review, power spectrum, topographic voltage. Both require that the signal be digitized by a separate EEG acquisition system. Both are software only products.

Both eemagine EEG and Persyst Spike Detector provide an automatic detection of spike events based on the EEG input and typical characteristics of such events. All parameters necessary to model spike activity are accessible in the eemagine EEG software.

Both eemagine EEG and IMAGEVUE EEG provide visualization of electrical brain activity based on EEG signals and a computer model of the head. IMAGEVUE correlates the activity with the MRI of the subject, whereas eemagine EEG provides an idealized rendered head surface model and an idealized MR image

with the software. The eemagine EEG software makes use of the single dipole fit method, whereas the IMAGEVUE EEG offers more complex brain modeling in addition to dipole fit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2000

Eemagine Medical Imaging Solutions
c/o Mr. Scott J. Pease, ASQ-CQA
Pease Consulting
W306 S8345 Chestnut Drive
Mukwonago, Wisconsin 53149

Re: K002631
Trade Name: Eemagine EEG Software
Regulatory Class: II
Product Code: GWQ
Dated: May 8, 2000
Received: August 23, 2000

Dear Mr. Pease:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002631

Device Name: eemagine EEG (Software)

Indications For Use:

The software is intended for use by a trained/qualified EEG technologist or physician on both adult and pediatric subjects for the visualization of human brain function by fusing a variety of EEG information with rendered images of an idealized head model and an idealized MRI image.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002631

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)